

GAVILYTE G TM - polyethylene glycol 3350, sodium chloride, sodium bicarbonate, potassium chloride and sodium sulfate anhydrous powder, for solution

GAVIS Pharmaceuticals, LLC

Rx only

DESCRIPTION

GaviLyte – G is a white powder in a 4 liter jug for reconstitution, containing 236 g polyethylene glycol 3350, 22.74 g sodium sulfate (anhydrous), 6.74 g sodium bicarbonate, 5.86 g sodium chloride and 2.97 g potassium chloride. When dissolved in water to a volume of 4 liters, GaviLyte – G (PEG-3350 (236 g) and Electrolytes for Oral Solution, USP) is an isosmotic solution, for oral administration, having a mildly salty taste. GaviLyte – G is administered orally or via nasogastric tube as a gastrointestinal lavage.

CLINICAL PHARMACOLOGY

GaviLyte – G induces a diarrhea which rapidly cleanses the bowel, usually within four hours. The osmotic activity of polyethylene glycol 3350 and the electrolyte concentration result in virtually no net absorption or excretion of ions or water. Accordingly, large volumes may be administered without significant changes in fluid or electrolyte balance.

INDICATIONS AND USAGE

GaviLyte – G is indicated for bowel cleansing prior colonoscopy and barium enema X-ray examination.

CONTRAINDICATIONS

GaviLyte – G is contraindicated in patients known to hypersensitive to any of the components. GaviLyte – G is contraindicated in patients with gastrointestinal obstruction, gastric retention, bowel perforation, toxic colitis, toxic megacolon or ileus.

WARNINGS

The lemon flavor pack is for use only in combination with the contents of the accompanying 4 liter container. No additional ingredients, e.g. flavorings, should be added to the solution. GaviLyte – G should be used with caution in patients with severe ulcerative colitis.

PRECAUTIONS

General

Patients with impaired gag reflex, unconscious, or semiconscious patients, and patients prone to regurgitation or aspiration should be observed during the administration of GaviLyte – G, especially if it is administered via nasogastric tube. If a patient experiences severe bloating, distention or abdominal pain, administration should be slowed or temporarily discontinued until the symptoms abate. If gastrointestinal obstruction or perforation is suspected, appropriate studies should be performed to rule out these conditions before administration of GaviLyte – G.

Information for Patients

GaviLyte – G produces a watery stool which cleanses the bowel before examination. Prepare the solution according to the instructions on the bottle. It is more palatable if chilled. For best results, no solid food could be consumed during the 3 to 4 hour period before drinking the solution, but in no case should solid foods be eaten within 2 hours of taking GaviLyte – G.

Drink 240 mL (8 oz.) every 10 minutes. Rapid drinking of each portion is better than drinking small amounts continuously. The first bowel movement should occur approximately one hour after the start of GaviLyte – G administration. You may experience some abdominal bloating and distention before the bowels start to move. If severe discomfort or distention occur, stop drinking temporarily or drink each portion at longer intervals until these symptoms disappear. Continue drinking until the watery stool is clear and free of solid matter. This usually requires at least 3 liters and it is best to drink all of the solution. Any unused solution should be discarded.

Drug Interactions

Oral medication administered within one hour of the start of administration of GaviLyte – G may be flushed from the gastrointestinal tract and not absorbed.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenic and reproductive studies with animals have not been performed.

Pregnancy

Category C. Animal reproduction studies have not been conducted with GaviLyte – G. It is also not known whether GaviLyte – G can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. GaviLyte – G should be given to a pregnant woman only if clearly needed.

Pediatric Use

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Nausea, abdominal fullness and bloating are the most common adverse reactions (occurring in up to 50% of patients) to administration of GaviLyte – G. Abdominal cramps, vomiting and anal irritation occur less frequently. These adverse reactions are transient and subside rapidly. Isolated cases of urticaria, rhinorrhea, dermatitis and (rarely) anaphylactic reaction have been reported which may represent allergic reactions.

Published literature contains isolated reports of serious adverse reactions following the administration of PEG-ELS products in patients over 60 years of age. These adverse events include upper GI bleeding from Mallory-Weiss Tear, esophageal perforation, asystole, sudden dyspnea with pulmonary edema, and “butterfly-like” infiltrates on chest X-ray after vomiting and aspirating PEG.

DOSAGE AND ADMINISTRATION

The recommended dose for adults is 4 liters of GaviLyte – G solution prior to gastrointestinal examination, as ingestion of this dose produces a satisfactory preparation in over 95% of patients. Ideally, the patients should fast for approximately three or four hours prior to GaviLyte – G administration, but in no case should solid food be given for at least two hours before the solution is given.

GaviLyte – G is usually administered orally, but may be given via nasogastric tube to patients who are unwilling or unable to drink the solution. **Oral administration** is at a rate of 240 mL (8 oz.) every 10 Minutes, until 4 liters are consumed or the rectal effluent is clear. Rapid drinking of each portion is preferred to drinking small amounts continuously.

Nasogastric tube administration is the rate of 20 to 30 mL per minute (1.2 to 1.8 liters per hour). The first bowel movement should occur approximately one hour after the start of GaviLyte – G administration.

Various regimens have been used. One method is to schedule patients for examination in midmorning or later, allowing the patients three hours for drinking and an additional one hour period for complete bowel evacuation. Another method is to administer GaviLyte – G on the evening before the examination, particularly if the patient is to have a barium enema.

Preparation of the solution: GaviLyte – G is prepared by filling the container to the 4 liter mark with water and shaking vigorously several times to ensure that the Ingredients are dissolved. Dissolution is facilitated by using lukewarm water. The solution is more palatable if chilled before administration. The reconstituted solution should be refrigerated and used within 48 hours. Discard any unused portion.

HOW SUPPLIED

GaviLyte – G is supplied in a disposable jug, in powdered form, for oral administration as a solution following reconstitution. Each jug has the attached lemon flavor pack, in powdered form, for the addition of the flavor packet by the pharmacist prior to dispensing.

Disposable Jug: polyethylene glycol 3350 236 g, sodium sulfate (anhydrous) 22.74 g, sodium bicarbonate 6.74 g, sodium chloride 5.86 g, potassium chloride 2.97 g and lemon flavor pack 2 g (optional). When made up to 4 liters volume with water, the solution contains PEG-3350 17.6 mmol/L, sodium 125 mmol/L, sulfate 40 mmol/L, chloride 35 mmol/L, bicarbonate 20 mmol/L and potassium 10 mmol/L.

STORAGE: Store in sealed container at 59° - 86°F. When reconstituted, keep solution refrigerated. Use within 48 hours. Discard unused portion.

NDC 43386-090-19

Manufactured by:

Novel Laboratories, Inc.

Somerset NJ 08873

Distributed by:

GAVIS Pharmaceuticals, LLC

Somerset NJ 08873

GLB-090-4L-00

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EXP:

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43386-090-19

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FILL TO THE TOP OF THE LINE ON BOTTLE

GaviLyte™ -G

(PEG-3350 (236g) and Electrolytes for Oral Solution, USP)

1. This preparation can be used with or without the lemon flavor pack. The pharmacist will add the lemon flavor pack prior to dispensing (see packet instructions).

2. Add lukewarm drinking water to the fill mark (4 liters) on the bottle. Do not add any other ingredients, flavors, etc.

3. Cap bottle securely and shake vigorously several times to ensure that the ingredients are dissolved.

4. For best results, no solid food should be consumed for the 3 to 4 hour period before drinking the solution, but in no case should food be eaten within two hours of taking GaviLyte-G.

5. Drink one 8 ounce (240 mL) cup of the solution rapidly every 10 minutes. A loose watery bowel movement should result in approximately one hour. Continue drinking until the entire contents (4 liters) have been consumed or as directed by physician.

NOTE: The solution is more palatable if chilled in the refrigerator before drinking. Keep reconstituted solution refrigerated. Use within 48 hours. Discard unused portion.

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Distributed by GAVIS Pharmaceuticals LLC Somerset, NJ 08873

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FILL TO THE TOP OF THE LINE ON BOTTLE

NDC # 43386-090-19

TO PHARMACIST AND PATIENT:

Mixing information is on the base label. Package insert may be removed before dispensing.

GaviLyte™ -G

PEG-3350 (236g) and Electrolytes for Oral Solution, USP

When reconstituted with water to a volume of 4 liters, this solution contains 125 mmol/L sodium, 10 mmol/L potassium, 40 mmol/L sulfate, 20 mmol/L bicarbonate, 35 mmol/L chloride and 17.6 mmol/L polyethylene glycol 3350.

Each disposable jug contains, in powdered form:

Polyethylene Glycol 3350	236 g
Sodium Sulfate (anhydrous)	22.74 g
Sodium Bicarbonate	6.74 g
Sodium Chloride	5.86 g
Potassium Chloride	2.97 g

Rx only

GAVIS™

PHARMACEUTICALS

GLB-090-4L-00

PULL DOWN TO OPEN

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